FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

MYLAN DEFENDANTS' MEMORANDUM IN SUPPORT OF COMPANION MOTION FOR SUMMARY JUDGMENT AND TO EXCLUDE EXPERT TESTIMONY

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Mylan Defendants move for summary judgment on all remaining claims and causes of action asserted against them by Plaintiffs in this MDL litigation. After three years of litigation, Plaintiffs have no admissible evidence that Digitek® tablets distributed by Mylan Defendants and allegedly consumed by Plaintiffs were defective. Because proof of defect is an essential element common to all Plaintiffs' claims and causes of action, Mylan Defendants are entitled to judgment as a matter of law in the remaining MDL cases.

Additionally, Mylan Defendants move, pursuant to Rule 702 of the Federal Rules of Evidence, for an order excluding the expert testimony of Mark Kenny, on the grounds that Mr. Kenny—the only expert designated to offer opinion testimony against Mylan Defendant—lacks sufficient qualifications for his opinions, and his opinions have no reliable basis in fact or methodology.

FACTUAL BACKGROUND[1]

This litigation originated with publicity surrounding Actavis' April 25, 2008 Digitek® recall. In November of 2007, Actavis found and removed 20 double-thick Digitek® tablets from

[1] Mylan Defendants incorporate by reference Defendants' General Background Statement of Key Factual Information Regarding Digitek ("Facts Statement"), Doc. No. 522, and all exhibits and authorities cited therein.

batch 70924A. The batch contained a total of 4.8 million tablets. Actavis released the batch for distribution on January 28, 2008, after further investigation and inspection uncovered no additional double-thick tablets.

Three months later, out of an abundance of caution, Actavis recalled batch 70924A and all other batches of Digitek® within expiry due to the theoretical possibility that double-thick tablets may have been commercially released. Following national advertising by plaintiff's firms, hundreds of Digitek® purchasers and consumers filed suit, citing the recall and seeking damages for injuries allegedly sustained as a result of ingesting defective Digitek® tablets.

Three years have now passed and, despite their numbers, not one plaintiff has produced evidence that the Digitek® tablets he or she received were defective.

PLAINTIFFS HAVE NO EVIDENCE OF DEFECT

I. Plaintiffs Must Prove that Digitek® Tablets Distributed by Mylan Defendants and Consumed by Plaintiffs Were Defective. [2]

As more fully briefed in Defendants' Motion for Summary Judgment and Supporting Memorandum, proof of defect is an essential element to all of Plaintiffs' causes of action against Mylan Defendants. But despite three years of litigation and extensive discovery, Plaintiffs have no admissible evidence—direct or indirect—to support their allegations that Mylan Defendants distributed and Plaintiffs consumed defective Digitek® tablets. Specifically:

- No Plaintiff has ever produced a double thick Digitek® tablet or a tablet containing doses of digoxin that are inconsistent with the labeled dose.
- No Plaintiff has produced physical or chemical testing evidence showing that the Digitek® tablets he or she received contained a manufacturing defect.

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[2] Mylan Defendants incorporate by reference Defendants' Motion for Summary Judgment and its supporting memorandum, including all exhibits, factual statements and authorities cited therein.

- No Plaintiffs' expert has offered admissible testimony that Digitek® tablets containing a manufacturing defect were released by Actavis for distribution and consumed by Plaintiffs.[3]

- No Plaintiffs' expert has offered admissible testimony that Digitek® tablets containing a manufacturing defect were distributed by Mylan Defendants and consumed by Plaintiffs.[4]

- The Digitek® recall cannot support an inference that all—or any—of the Digitek® tablets that Mylan Defendants distributed and that Plaintiffs allegedly consumed contained a manufacturing defect.[5]

- Allegations of adulteration in regulatory documents cannot support an inference that Digitek® tablets manufactured by Actavis contained a manufacturing defect.[6]

- Even if Plaintiffs had established valid claims against Actavis, they have not established a basis for imposing any independent liability against Mylan Defendants, who simply distributed Digitek® as finished pharmaceutical product.[7]

Plaintiffs have had ample time to produce evidence that Mylan Defendants distributed and Plaintiffs actually consumed defectively manufactured Digitek® tablets. Because they cannot do so, Mylan Defendants are entitled to judgment as a matter of law on all remaining claims and causes of action in this MDL proceeding.

PLAINTIFFS' ONLY EXPERT DESIGNATED TO RENDER OPINIONS AGAINST MYLAN DEFENDANTS, MARK KENNY

I. The Testimony of Plaintiffs' Only General Liability Expert to Offer Opinions About Mylan Defendants Is Unreliable.[8]

The only Plaintiffs' general liability expert to offer any opinion about Mylan Defendants in this litigation is Mark Kenny. In his report, Mr. Kenny opines that Mylan Defendants lacked

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3 *See* Defendants' Motion for Summary Judgment and Defendants' Motion to Exclude General Liability Experts.

4 *See id.*

5 Defendants' Memorandum in Support of Defendants' Motion for Summary Judgment, 13-15.

6 *Id.* at 8-13.

7 Actavis owns the ANDA for Digitek® and manufactured the product in its final finished and packaged form. Mylan Defendants were not involved in the design, approval or manufacture of Digitek®.

8 Mylan Defendants incorporate by reference Defendants' Motion to Exclude Plaintiffs' General Liability Experts and its supporting memorandum, including all exhibits, factual statements and authorities cited therein

adequate control systems for qualifying and monitoring contract manufacturers.[9] He based his opinion on the following three assumptions: (1) there was no agreement in place between Actavis and Mylan that established the parties' respective responsibilities for Digitek® cGMP compliance; (2) there were no procedures in place between Mylan and Actavis for the handling of Digitek® product complaints; and (3) Mylan would have detected alleged cGMP issues at Actavis prior to FDA, if it had conducted more frequent audits.[10]

First, Mr. Kenny is not qualified to express opinions about the regulatory requirements and industry standards governing the distribution of finished pharmaceutical products.[11] Mr. Kenny dedicates only a single page of his 35-page report to the Mylan Defendants, and he admits that he was retained by the PSC to specifically determine whether *Actavis* complied with Good Manufacturing regulations and whether *Actavis* released adulterated products.[12]

Second, Mr. Kenny's testimony demonstrates a complete lack of diligence on his part in the methodology he employed to develop his few opinions about Mylan Defendants. Mr. Kenny failed to conduct even a cursory investigation into the relationship between Actavis and Mylan Defendants with respect to the distribution of Digitek®.

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Q. How is it that Mylan sold DIGITEK?
A. Some type of agreement, verbal or written agreement, would have to be reached, and then they would sell the product. And I suppose there is -- there is some licenses that have to be obtained from the FDA, licenses which I'm not familiar with.
Q. Well, tell me in this situation what you have seen that tells you how it is that DIGITEK

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9 Kenny Rep. 33.
10 This last assumption is pure speculation. Kenny offers no explanation or support for his assertion that Mylan would have been able to detect cGMP violations at Actavis where FDA did not.
11 Kenny Dep., Vol. I 181:12-182:5, 256:7-257:7; Vol. II 499:11-21, 500:24-501:12.
12 Kenny Dep., Vol. II 461:25-462:6; Kenny Rep. 5.

19 came to be sold by Mylan.
20 A. I -- I didn't go back that far in
21 terms of reviewing that documentation. [13]

And he did not educate himself on the regulatory obligations of the various classes of distributors under FDA regulations because he "[didn't] know if it's important or not...."[14]

He also failed to conduct a thorough review of the 1999 Digitek® Supply & Distribution Agreement, which defined the roles and responsibilities of the parties with respect to cGMP compliance and complaint handling—two of the three alleged deficiencies identified by Kenny in his report.[15]

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7 A. There was a supply agreement. I have
8 not read the supply agreement.
9 Q. Why not?
10 A. Well, I didn't see it in the records.
11 Q. Did you ask for it?
12 A. I did not ask for it.
13 Q. So in all of the work you've done, all
14 hours that you've billed, all of the time that
15 you've spent preparing for your report and writing
16 your report and giving your deposition, preparing
17 for your deposition, both on June 29, 2010 and again
18 today on February 16, 2011, you've never asked for
19 any supply agreement between Mylan and Actavis,
20 correct?
21 A. I don't recall asking specifically for
22 a supply agreement.
23 Q. So the answer to my question is no, I
24 have not?
25 A. No, I have not.[16]

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13 *Id.* at 333:10-21, 335:1-336:7, 369:18-370:12.
14 *Id.* at 500:4-501:11.
15 *Id.* at 335:1-336:7, 339:2-15, 369:18-370:12; Kenny Rep. 33-34.
16 Though Kenny originally testified that he had not reviewed or even requested to review the Supply and Distribution Agreement, he later changed his testimony, stating that he had "blitzed through it. *Id.* at 511:9

Finally, some of the opinions expressed by Mr. Kenny in his report may not even be his own. At deposition, Defendants discovered that a colleague of Mr. Kenny's, a Mr. Sal Romano, co-authored the report ultimately submitted under only Kenny's name.[17]

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Q. On Page 2 [of your draft report], you state in the introduction that it's not only you but it's Mark Kenny and Salvatore Romano who have been engaged by Motley Rice to prepare an expert report?
A. That is correct.
Q. That you, Mark Kenny, and Salvatore Romano had been engaged to participate in a legal deposition?
A. That is correct.
Q. And that you, Mark Kenny, and Salvatore Romano, have been engaged to testify as an expert witness at trial?
A. Yes.
Q. And then you refer to the expert opinion as "our expert opinion," right?
A. That is correct.

Kenny testified that Mr. Romano withdrew as an expert 10 days prior to Plaintiffs' disclosure of Kenny's report, allegedly due to scheduling conflicts that prevented him from appearing for deposition.[18]

In addition to the reasons outlined in Defendants' Motion to Exclude Plaintiffs' General Liability Experts, this Court should exclude the testimony of Mark Kenny as it pertains to Mylan Defendants on the grounds that Mr. Kenny lacks sufficient qualifications for his opinions, and his opinions have no reliable basis in fact or methodology. Mr. Kenny's opinions regarding the absence of an agreement establishing the responsibilities of Actavis and Mylan are contradicted by the Supply and Distribution Agreement, a document he admittedly "blitzed through." Further,

[17] *Id.* at 485:1-486:16, 487:12-25, 488:11-25.
[18] *Id.* at 398:10-399:5, 489:1-6, 569:20-570:1-11.

his lack of understanding of Mylan's legal obligations as a pharmaceutical distributor renders any opinion on the question of legal duty speculative.

CONCLUSION

FOR THE FOREGOING REASONS, Mylan Defendants respectfully ask this Court to enter an order granting Mylan Defendants' Motion for Summary Judgment on all remaining claims and causes of action asserted against them by Plaintiffs in this MDL proceeding. Mylan Defendants also ask this Court to enter an order excluding the expert testimony of Mark Kenny, the only Plaintiffs' expert to offer opinions concerning Mylan Defendants.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 3, 2011, a copy of the foregoing **DEFENDANTS' MEMORANDUM IN SUPPORT OF COMPANION MOTION FOR SUMMARY JUDGMENT AND TO EXCLUDE TESTIMONY** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Respectfully submitted,

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